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In re Application of	:	
Jan Zur Megede, et al	:	
Serial No.: 09/899,575	:	DECISION ON PETITION
Filed: July 5, 2001	:	
Attorney Docket No.: PP01631.102	:	

This letter is in response to the Petition under 37 C.F.R. 1.144 filed September 6, 2005, to review the restriction requirement and have all of the sequences in Group II searched.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 and that the Office set forth a restriction requirement under 35 U.S.C. 121, of claims 1-97 in an office action mailed January 5, 2005. The groupings are reproduced below:

> Group I, claims 1, 13, 14, 59-73 and 97, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 30-32, 62 and 103;
> Group II, claims 2-6 and 38-46, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 46, 119-127, and 131-133;
> Group III, claims 7 and 8, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 51 and 99;
> Group IV, claims 9 and 10, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 55, 57, 96, 101, and 134-135;
> Group V, claim 11, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO: 58;
> Group VI, claim 12, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO: 60;
> Group VII, claim 15, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 64 and 66;
> Group VIII, claims 16 and 17, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 68 and 70;

Group IX, claims 18-21, 33, 34, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 72, 74, 91, 105, and 107;
Group X, claims 22 and 23, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 76 and 78;
Group XI, claims 24-26, 35, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 80, 81, 83, 93, 94, 109, 111, and 113;
Group XII, claim 27, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 85 and 113;
Group XIII, claims 28 and 29, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 87 and 115;
Group XIV, claims 30-32, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NOS: 89 and 117;
Group XV, claims 36-37, drawn to an expression cassette comprising a polynucleotide sequence of SEQ ID NO: 96;
Group XVI, claims 47-51, drawn to a polynucleotide depicted in SEQ ID NO: 33;
Group XVII, claims 52-56 and 74-77, drawn to a polynucleotide depicted in SEQ ID NO: 45;
Group XVIII, claims 57-58, drawn to a polynucleotide depicted in SEQ ID NO: 128;
Group XIX, claims 78-90 and 92-96, drawn to a method of DNA immunization in a subject or generating an immune response in a subject;
Group XX, claim 91, drawn to a method of generating an immune response in a subject using an HIV polypeptide.

The examiner reasoned that Groups I-XVIII are patentably distinct products. The examiner stated that the polynucleotides in Groups I-XVIII have a different function and different effect. Furthermore, the information provided by any of the polynucleotides of Group I can be used to make a materially different polypeptide than the polypeptide encoded by the polynucleotides in groups II-XVIII and vice versa. In addition, a sequence having 90 % sequence identity to a sequence presented in Group I encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with a polynucleotide in Groups II-XVII and vice versa. In addition, the polynucleotides that fall within the scope of Group I cannot be made by methods for producing the polynucleotides of Groups II-XVIII and vice versa. Furthermore, searching the inventions of Groups I-XVIII together would impose a serious burden. In the instant case the search of the polynucleotides in Groups I-XVIII are not coextensive. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Thus, the examiner concluded, to search Groups I-XVIII together would be burdensome.

The examiner next discussed Groups XIX and XX as unrelated. In the instant case, the examiner stated that the specification does not disclose that these methods would be used together. The method of DNA immunization (Group XIX) and the method of producing an immune response to recombinant proteins (Group XX) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material.

Moreover, the methodology and materials necessary for DNA immunization differ significantly for each of the materials. For DNA immunization, a mammal may be used. For producing recombinant proteins for use *in vivo*, *in vitro* prokaryotic cells may be used. Therefore, each method is divergent in materials and steps. For these reasons, the inventions of Groups XIX and XX are patentably distinct.

Inventions I and Inventions XIX and XX are related as product and process of use. In the instant case, the expression cassette of Group I can be used to make recombinant proteins as in Group XX as opposed to its use in a DNA immunization method in Group XIX.

The examiner argued that searching Groups I and XIX and XX together would impose a serious search burden. The examiner argued that the inventions are classified in different places and that a search for polynucleotides and the method of DNA immunization and method of recombinant proteins are not co-extensive. The examiner argued that Group I encompasses molecules which are claimed in terms of sequence identity in regard to SEQ ID NOS: 30-32, which are not required for the search of either Group XIX or Group XX. In contrast, the search for Group XIX or XX would require a text search for the method of DNA immunization in addition to polynucleotide search of sequences with 90 % sequence identity of SEQ ID NOS: 30-32. Prior art which teaches a polynucleotide that has 90 % sequence identity of SEQ ID NOS: 30-32 would not necessarily be applicable to the method of using sequences having at least 90 % sequence identity of SEQ ID NOS: 30-32. Moreover, even if the polynucleotides were known, the method of DNA immunization or producing recombinant proteins using the product may be novel and unobvious in view of the preamble or active steps.

Next the examiner argued that Inventions II-XVIII and either Inventions XIX or XX are unrelated because the product of Groups II-XVIII is not used or otherwise involved in the process of Group XIX or XX.

In addition, the examiner stated that if applicants elect from Groups I-IV and VII-XIV, a further restriction is required because the Groups read on patentably distinct sequences. The examiner stated that this was a restriction requirement to a single sequence and not an species election requirement. The examiner then listed each group of claims and listed the sequences corresponding to each group and required applicant to pick a group and a sequence from that group.

The examiner stated that there were no claims which encompassed a generic HIV polypeptide, which indicates that the SEQ ID NOS are independent and there is no disclosure of relationship (percent sequence identity) in the specification between the claimed sequences in each group.

The examiner stated that one sequence constitutes a reasonable number for examination purposes under the present conditions. At present, the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of one sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims.

Applicants' response filed March 10, 2005 elected Group II and SEQ ID NO: 120. Applicants traversed the requirement on the grounds that it would not be unduly burdensome to search sequences classified in elected Group II together.

Applicants argued that within each Group it is clear that each and every sequence encodes a particular HIV polypeptide. Group II, for instance, includes sequences encoding Env polypeptides. Furthermore, applicants were not aware that the specification was required to set forth the percent sequence identity as between the claimed sequences. Given that they are clearly described as "Env-encoding", their relationship to each other is clear. As indicated in MPEP 803.04, applicant argues, they feel that the MPEP states that they are entitled to have up to ten sequences searched.

Thus, the applicant concluded, all sequences encoding HIV Env proteins may be properly examined together. Furthermore, the homology between the various sequences of Group II is very high, as illustrated by the attached alignment of SEQ ID NOS: 120 and 121. In view of the high degree of homology between the sequences, it would not be burdensome to examine more than one sequence in each group. Certainly, SEQ ID NOS: 120 and 121 are so similar that it would not constitute an undue burden on the Office to examine them together.

On June 2, 2005, the examiner issued a non-final Office action and responded to applicant's arguments for traversal. The examiner argued that MPEP 803.04 is only a guideline and not legally binding. Moreover, the "ten" nucleotide policy evolved in response to the large number of nucleotide sequences being disclosed in SPDI applications, of which this application is clearly not a member. Thus, the examiner concluded that the ten nucleotide sequence guideline is not applicable. Next the examiner stated that currently two criteria exist for the determination of proper restriction requirements. The invention must be independent or distinct as claimed and there must be a serious burden on the examiner if restriction is not required. The examiner stated that the basis for restriction was clearly stated in the previous Office action. Each nucleotide sequence is directed toward structurally different envelope glycoproteins and would require separate searches. Applicants further asserted that the various envelope sequences are closely related, but failed to provide any diagram or sequence alignments demonstrating this fact. The examiner then made the requirement FINAL.

On September 9, 2005, applicants filed a response to the non-final Office action. Applicants argued that the examiner had not met the burden of establishing a proper restriction. Applicants argued that there is a high homology between the sequences and the examiner has not shown that it would impart a serious burden to examine the sequences together. Applicants argued that the examiner had not even shown that the nucleotide sequences encode "structurally different envelope glycoproteins". In fact, the sequences exhibit high homology to each other and a search of the art for sequences relevant to any of SEQ ID NOS: 46, 47, 49, 97, 119, 120, 121, 122, 123, 124, 125, 126, 127, 131, 132, or 133 would necessarily reveal art relevant to the other sequences.

Applicants again directed the examiner to the alignment of SEQ ID NOS: 120 and 121. Applicants also submitted evidence, they stated, to SEQ ID NOS: 46 and 47. They stated that these sequences exhibit high homology to each other.

Applicants stated that in view of the high degree of homology to each other, it is clear that searching the art for the full-length of any of these sequences would necessarily reveal references relevant to all other sequences and, as such, it would not impart a serious burden on the examiner to search them together. They argued that it would be a serious financial burden on them.

The petition to review the restriction requirement mailed January 5, 2005 was filed on September 6, 2005.

DISCUSSION

The application, file history and petition have been considered carefully. In the Petition, Applicants request consideration of all of the sequences in Group II, specifically, SEQ ID NOS: 46, 119-127, and 131-133. Applicants petitioned to have all of the sequences in Group II examined and not be limited to just SEQ ID NO: 120.

Applicants reiterated the above record and stated that by the examiner restricting them to a single sequence, the Office has prevented applicants from claiming the full scope of their invention. The applicant then cited legal precedents which refer to lack of unity of invention. Applicants argued that in the case at hand, all Group II sequences share a common utility and possess a substantial structural feature essential to that utility.

Applicants continue to argue that the claimed polynucleotides do not differ in structure or function, but that they differ only in sequence. Accordingly, the assertion that the sequences are structurally different polypeptides is in error and cannot support the restriction. Therefore, applicants concluded that the sequences in group II possess unity according to MPEP 803.02 and that the requirement has prevented applicants from claiming the full scope of their invention and that restriction among the different Env-encoding sequences should be withdrawn. Applicants also argue that the restriction is a (future) financial burden on applicants.

Next applicants state that in reference to the examiner's statement about MPEP 803.04 not applying to SPDI applications that the examiner is incorrect because MPEP 2434 states that applicants can claim up to ten sequences in an application.

Applicants are not correct that the examiner has failed to apply a proper standard for restriction in this case. The examiner has properly established why claims 2-6 and 38-46 read on patentably distinct sequences. The sequences are indeed patentably distinct as is shown by their own sequence listings. A comparison of the different sequences shows that there is no common core between the sequences. If one is to look at the sequences there is no apparent similarity between the different sequences.

As far as applicants' arguments concerning unity of invention, this does not apply in this case since this argument relates to Markush group claims.

In regard to applicant's comments concerning MPEP 803.04 and MPEP 2434, that these citations support applicant's arguments that up to ten sequences can be claimed and examined together,

this is not well taken. Applicant's sequences share no homology whatsoever. As stated above, the sequences differ in their sequences (structures). A review of the sequences themselves reveals this fact. No common core can be found with the sequences. In many of them it is quickly apparent that even the first nucleic acids in the first part of the sequence do not match up with the first nucleic acids in the other sequences. Further, as stated by the examiner in the Office action of June 2, 2005, these citations are only applicable to SPDI applications, of which this application is clearly not.

For these reasons the restriction requirement is found to be proper.

DECISION

Applicants petition under 37 CFR 1.144 is **DENIED** for the reasons set forth above.

The application will be forwarded to the examiner for further consideration of the reply filed September 9, 2005, not inconsistent with this decision.

Any request for reconsideration of this decision must be filed within TWO MONTHS of the mailing date thereof in order to be considered timely.

Should there be any questions regarding this decision, please contact Special Program Examiner William R. Dixon, Jr., by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-0519 or by Official Fax at 571-273-8300

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